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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,302	07/03/2003	Gary H. Posner	2938-116	3192

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EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/612,302

Applicant(s)

POSNER ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20,23-35,46-52 and 60-64 is/are pending in the application.
- 4a) Of the above claim(s) 11,21,22,24-35,46-52 and 60-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10,12-20 and 23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

2. Claims 1-20, 23-35, 46-52 and 60-64 are pending in the present application. Claims 11, 21, 22, 24-35, 46-52 and 60-64 stand withdrawn from further consideration as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 112

3. The rejection of claims 19 and 20 under 35 USC 112, second paragraph is withdrawn.
4. The rejection of claim 10 under 37 CFR 1.75(c) is withdrawn.
5. The rejection of claim 18 under 37 CFR 1.75(c) is maintained.

The instant claim recites compound such as I(v), I(w), I(x), I(y) and I(gg) not encompassed by parent claim 1.

Note: According to parent claim 1, R⁴ cannot be alkyl.

Claim Rejections - 35 USC § 102

6. The rejection of claims 1-4, 12-14, 17 and 23 under 35 USC 102(b) over Posner et al. (J. Med. Chem., 1999) is withdrawn.

Claim Rejections - 35 USC § 103

7. The rejection of claims 1-10, 12-20 and 23 under 35 USC 103(a) over DeLuca et al. (US 4,927,815) is maintained.

Applicant argues (a) the solution of finding new vitamin D analogues provided by DeLuca is completely different to that provided by the present invention; (b) the phenyl-sulfone compound of the cited prior art are only disclosed as an intermediate used in preparation of the active compounds and (c) the only sulfone containing vitamin D compounds prepared by the prior art, compounds 29 and 30, have an insertion of extra methylene units into the side chain that differs from the present invention. Applicant's argument was considered but not persuasive for the following reasons.

First, there is no requirement that the prior art must suggest that the compound(s) will have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness. In re Dillon, 919 F.2d 688, 696, 16 USPQ 2d 1897, 1904 (Fed. Cir. 1990). An obviousness rejection is proper as long as the prior art suggests a reason or provides a motivation to make the claimed invention. The motivation to make the claimed compounds is based on the teaching by the cited prior art that the compounds are intermediates in the production of active vitamin D compounds.

As discussed in the previous Office Action, the reference teaches vitamin D₃ derivatives having a phenylsulfone containing side chain (see col. 4, lines 45-63). Like the claimed compounds, the prior art compound is substituted in the 23-position with a phenylsulfone moiety and an alkyl moiety. According to the prior art, said alkyl group is inclusive of straight chain or branched alkyl radical of 1 to 10 carbons (see col. 6, lines 20-22). Based on the teachings of the prior art, the claimed compounds wherein one of R⁶ or R⁷ is an alkyl group would have been obvious to the skilled artisan in the art at the time of the present invention. The motivation to make any of the species of the prior art genus is based on the reasonable expectation that the compounds would be useful in the production of vitamin D derivatives having biological properties as taught by DeLuca.

Applicant also argues the prior art compounds 29 and 30 have an insertion of extra methylene units. The examiner notes that the prior art compounds 29 and 30, like the claimed compounds have a 23-phenylsulfone unit and a 23-alkyl group. Unlike the claimed compounds, the exemplified compounds have a C₇ group. However, modification of said exemplified prior art compounds by substitution of said exemplified C₇ group with C₁₋₄ alkyl groups would be obvious to the skilled artisan based on the teaching of C₁₋₁₀ alkyl groups by the cited prior art. As stated above, the motivation is based on the teaching by the cited prior art that said compounds are useful in the preparation of biologically active vitamin D compounds.

For these reasons and those given in the previous Office Action, the rejection of claims 1-10, 12-20 and 23 under 35 USC 103(a) over DeLuca et al. (US 4,927,815) is maintained.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB
March 13, 2006